THE UNITED STATES PATENT AND TRADEMARK OFFICE

ICATION

MAIL STOP:

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OF:

WITSCHEL ET AL.

CONFIRMATION No.:

4151

SERIAL No. 09/936,356 GROUP ART UNIT:

1626

FILED:

SEPTEMBER 11, 2001

EXAMINER: R. L. Anderson

For:

TRICYCLIC BENZOYLPYRAZOLE DERIVATIVES

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PETITION UNDER 37 C.F.R. \$1.144

Sir:

Applicants hereby petition to the Honorable Commissioner to review the restriction requirement in application Serial No. 09/936,356 which issued on February 16, 2005:

STATEMENT OF MATERIAL FACTS:

- The application was filed in the U.S. under 35 U.S.C. §371 on September 11, 2001, as a U.S. national stage application of international application PCT/EP 00/02010 which was filed on March 08, 2000.
- A first requirement to elect a single invention and to restrict the application accordingly, as well as a requirement to elect a single species, was mailed on January 17, 2003.
- Applicants filed a timely reply on February 04, 2003 (date of the Certificate of Mailing). Applicants complied with the Examiner's election and election of species requirements, and presented reasons why traversal of the Examiner's restriction requirement was deemed to be proper.
- The Examiner issued a first Office action on the merits on December 31, 2003, reiterating the restriction requirement, and making the restriction requirement final.

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- 5. Applicants filed a timely reply on June 30, 2004 (date of the Certificate of Mailing) addressing the issues raised in Office action on the merits of the invention, and including a further request for reconsideration of the Examiner's restriction requirement.
- 6. The Examiner issued a final action on the merits on February 16, 2005, in which the Examiner indicated that the restriction requirement as well as the rejection on the merits of applicants' claims were being maintained.
 - This Petition follows.
- 8. A request for reconsideration of the final rejection of applicants' claims is submitted along with this petition. Applicants have as yet not submitted a Notice of Appeal under 37 C.F.R. §41.31 in this application.

STATUS OF THE CLAIMS:

Claims 1, 5 to 16, 18 to 21 and 23 are currently pending in the application. Claims 18 to 21 stand withdrawn from further consideration. Claims 7, 9 to 11 and 13 stand allowed, and Claims 1, 5, 6, 8, 12, 14 to 16 and 23 stand rejected. A copy of the pending claims is found in the attached Appendix.

MEMORANDUM

The present application was filed under 35 U.S.C. §371 as a U.S. national stage application and, pursuant to PCT Article 27(1) which provides:

No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and its Regulations.

A requirement to restrict the present application is, accordingly, governed by the unity of invention rationale which is set forth in PCT Rule 13.

PCT Rule 13.1 which defines the requirement of unity of invention provides that an international application, and correspondingly a national stage application, either shall relate to one invention only, or shall relate to a group of inventions where the inventions are so linked as to form a single general inventive concept. Additionally,

PCT Rule 13.2 specifies that the requirement of unity of invention is considered fulfilled by a group of inventions when the inventions are in a technical relationship which <u>involves</u> "one or more of the same or corresponding special technical features". PCT Rule 13.2 also specifies that the "special technical features" of a claimed invention are those technical features which define the contribution which the claimed invention, when considered as a whole, makes over the prior art²). In order to determination whether the circumstances circumscribed in PCT Rule 13.2 are met and whether the requirement of unity of invention is fulfilled by a group of inventions it is, therefore, necessary

- firstly, for each of the claimed inventions independently: to determine which of the technical features of the particular claimed invention, considered as a whole, define a contribution of said invention over the prior art, ie. a determination of the "special technical features" of said invention, and
- subsequently, for the group of claimed inventions: to determine whether the inventions which are claimed in the application are in a technical relationship which involves one or more of the same or corresponding special technical features.

Initially, the Examiner required election of, and restriction of the application to, a single invention listing eight exemplary groups of claims relating to

- a) various groups of compounds $(I)^3$, depending upon the nature of, for example, X, Y R⁹ and R¹⁰;
- b) various groups of compounds $(VI)^4$, depending upon the nature of, for example, X, Y R⁹ and R¹⁰;
- c) various groups of compounds $(IX)^{5}$, depending upon the nature of, for example, X, Y R^9 and R^{10} ;
- d) various groups of compounds $(XV)^{6}$, depending upon the nature of, for example, X, Y R^{9} and R^{10} ; and

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¹⁾ PCT Rule 13.2, first sentence.

²⁾ PCT Rule 13.2, second sentence.

³⁾ Cf. Groups I. to V., page 2, line 10, to page 4, line 22, of the Office action dated January 17, 2003.

⁴⁾ Cf. Groups VI. to VII., page 5, lines 1 to 8, of the Office action dated January 17, 2003.

⁵⁾ Cf. Groups VIII. to IX., page 5, lines 9 to 16, of the Office action dated January 17, 2003.

⁶⁾ Cf. Groups X. to XI., page 5, line 17, to page 6, line 2, of the Office action dated January 17, 2003.

e) various groups of compounds $(XVI)^{7}$, depending upon the nature of, for example, X, Y R^9 and R^{10} .

The Examiner argued⁸⁾ that the claims lacked unity of invention under PCT Rule 13 for lack of a significant structural element which qualified as the special technical feature that defines a contribution over the prior art, citing the disclosure of WO 97/19087 and of EP 0 860 441 as support for the position⁹⁾. The Examiner also pointed out that the "vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a burden on" the examination¹⁰⁾.

The Examiner' requirement that applicants' restrict the application is deemed to be in error

- (1) because unity of invention within the meaning of PCT Rule 13 does not require the presence of "a significant structural element which qualifies as the special technical feature that defines a contribution over the prior art", and
- (2) because the disclosure of WO 97/19087 and of EP 0 860 441 fail to support that applicants' inventions lack a technical relationship involving one or more of the same or corresponding special technical features.

Rule 13.2 specifically points out that the requirement of unity of invention is considered to be met when the claimed inventions are in a technical relationship involving one or more of the same or corresponding special technical features. A requirement that one particular special technical feature be present which reside in a significant structural element of the compounds is, therefore, deemed to be a limitation of the rights provided by PCT Rule 13, and is deemed to be inconsistent with the provisions of PCT Article 27(1).

Applicants' invention relates to compounds (I) and intermediates for the preparation of the compounds (I) which have the following sub-structure in common:

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⁷⁾ Cf. Groups XII. to XIII., page 6, lines 3 to 10, of the Office action dated January 17, 2003.

⁸⁾ Cf. page 6, lines 19 to 21, of the Office action dated January 17, 2003.

⁹⁾ Cf. page 6, line 21, to page 7, line 2, of the Office action dated January 17, 2003, page 2, line 21, to page 3, line 3, of the Office action dated December 31, 2003, and page 2, lines 12 to 16, of the Office action dated February 16, 2005.

¹⁰⁾ Cf. page 7, lines 6 to 8, of the Office action dated January 17, 2003, page 3, lines 3 to 9, of the Office action dated December 31, 2003, and page 2, lines 20 to 22, of the Office action dated February 16, 2005.

wherein Y designates, together with the carbon atoms to which it is attached, a 1,2-isoxazole ring which is saturated or partially saturated or unstaturated, and P is a radical IIa (formula (I)), hydroxyl or a radical which can be removed by hydrolysis (formula (VI)), halogen, C_1 — C_6 —alkylsulfonyloxy, C_1 — C_6 —haloalkylsulfonyloxy or phenylsulfonyloxy, where the phenyl ring is optionally substituted (formula (IX)), amino (formula (XV)) or cyano (formula (XVI)).

The disclosure of WO 97/19087 provides for compounds which comprise a moiety

wherein the substituent marked as # corresponds to the group P of applicants' compounds. The respective moiety of the compounds addressed in WO 97/19087 differs structurally from the tricyclic substructure of applicants' compounds in the specific spacial arrangement of # relative to the condensed bicyclus.

The disclosure of EP 0 860 441 provides for compounds which comprise a moiety

wherein the substituent marked as # corresponds to the group P of applicants' compounds. The respective moiety of the compounds addressed in EP 0 860 441 also differs structurally from the tricyclic substructure of applicants' compounds in the specific spacial arrangement of # relative to the condensed bicyclus. The respective moiety of the compounds addressed in EP 0 860 441 further differs from the tricyclic substructure of applicants' compounds because it comprises an A,B-containing 6-membered ring in the position where

applicants' formula requires a 1,2-isoxazole ring which is saturated or partially saturated or unstaturated.

In light of the clear distinctions between the tricyclic substructure

of applicants' compounds and the tricyclic moieties of the compounds which are addressed in WO 97/19087 and in EP 0 860 441, the particular substructure of applicants' compounds clearly represents one or more of the same or corresponding special technical features which define the contribution which each of applicants' compounds makes over the prior art.

Moreover, applicants' compounds are in a technical relationship which involves the features of the tricyclic substructure because the compounds of applicants' formulae (XVI), (XV), (IX) or (VI) in which P denotes cyano, amino, halogen, C_1 - C_6 -alkylsulfonyloxy, C_1 - C_6 -haloal-kylsulfonyloxy or phenylsulfonyloxy, hydroxyl or a radical which can be removed by hydrolysis, are intermediates which incorporate the tricyclic substructure into the final product of formula (I).

The foregoing shows that the compounds addressed in applicants' claims are in a technical relationship and that the technical relationship involves one or more of the same or corresponding special technical features. Applicants' claims therefore clearly meet the circumstances outlined in PCT Rule 13.2 in which the requirement of unity of invention is to be considered fulfilled.

In the final action, the Examiner additionally argued that "even is unity of invention under 37 CFR 1.475(a) is not lacking, which it is, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations: ..."11). However, if the provisions of 37 C.F.R. §1.475(b) limited the rights provided by PCT Rule 13, as the Examiner would have it, 37 C.F.R. §1.475(b) would be inconsistent

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¹¹⁾ Cf. page 2, line 22, to page 3, line 14, of the Office action dated February 16, 2005.

with the provisions of PCT Article 27(1). The Examiner's position that 37 C.F.R. §1.475(b) supports her finding of lack of unity of invention is, therefore, also not deemed to be well taken.

CONCLUSION

In light of the foregoing it is urged that applicants' claims as presently pending in this case meet the unity of invention requirement of PCT Rule 13. It is therefore requested that the Examiner's restriction requirement be withdrawn, that Claims 18 to 21 be rejoined with Claims 1, 5 to 16 and 23, and that the application be returned to the Examiner for examination of all of the claims.

REQUEST FOR EXTENSION OF TIME:

A request for a <u>one</u> month extension of time under 37 C.F.R. §1.136(a) and the respective fee under 37 C.F.R. §1.17(a)(1) are submitted by applicants along with their reply of even date with this petition.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,

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Encl.: CURRENT CLAIMS (Appendix I)

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